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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,044

08/01/2005

Giorgio Mari

P70417US0

5665

136 7590 12/17/2009

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EXAMINER

CHRISTIAN, MARJORIE ELLEN

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

12/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,044	Applicant(s) MARI ET AL.	
	Examiner MARJORIE CHRISTIAN	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12 and 14-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/1/2009 has been entered and fully considered.
2. **Claims 1, 3-10, 12, 14-21** are pending and have been fully considered.

Claim Rejections - 35 USC § 102/103

3. **Claims 1, 3, 7-10, 12, 16-18, 20-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO00/54873, BORMANN et al. with further evidence from EP 0 542 655, MAJUREL.**

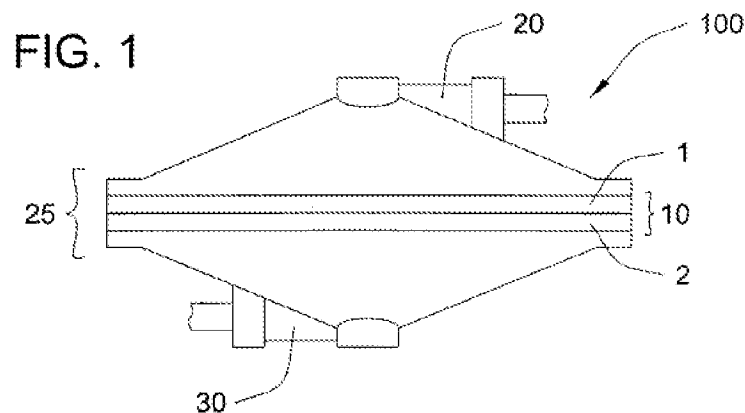
As to **Claims 1, 12, 20-21**, BORMANN discloses a filter device for the depletion of the leukocyte content from blood products (Abstract) comprising a housing (Fig. 1-2, Ref. 100) with an inlet (20) and an outlet (30) port and, within said housing, more than two porous elements (Pg. 16, Lines 25-28, Fig. 2-3, Ref. 1, 2) *adapted for* removing leukocytes, each porous element comprising multiple layers of filtering material (Pg. 11, Lines 13-14, Claim 18), wherein the more than two porous elements have a different hydrophilicity (Pg. 12, Lines 5-15), wherein the first porous element has a different hydrophilicity than the successive filter elements, and it is implicit that the difference is a first porous element (closer to inlet) has a higher hydrophilicity than the successive filter elements in the direction of flow, from inlet to outlet (Page 12, Lines 6-9, Pg. 11, Lines 15-28, Figs. 1-3). Further, BORMANN discloses the difference between the hydrophilicity of the inlet porous element (1) and outlet porous element (2), as

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measured by the CWST of the material is about 20dyn/cm (Pg. 12, Lines 10-15); and that the first porous element has hydrophilicity, as measured by the CWST, of greater than 63dyn/cm (Pg. 12, Lines 6-9).

However, it is also well known by a person having ordinary skill in the art to increase the hydrophobicity of the membranes from inlet to outlet in a leukocyte depletion filter to increase efficiency, as evidenced by MAJUREL. MAJUREL discloses a filtration device with different layers having increasing hydrophobicity from inlet to outlet, the increasing hydrophobicity of the layers improves the separation of blood components (Abstract). Further, it has been generally recognized that to shift location of parts when the operation of the device is not otherwise changed is within the level of ordinary skill in the art. *In re Japikse*, 86 USPQ 70; *In re Gazda* 104 USPQ 400.

Further, it would be obvious to one of ordinary skill in the art to use the teachings of these references to arrive at applicant's invention because it produces no more than predictable results. See *KSR Int'l. v. Teleflex Inc.*, 127 S. Ct. 1727, 1732, 82 USPQ2d 1385, 1390 (2007). "it is commonsense that familiar items have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle". "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.



As to **Claim 3**, BORMANN discloses each porous element comprises at least two adjacent layers of filtering material (Pg. 11, Lines 12-14).

As to **Claim 7**, BORMANN discloses said porous elements are made of fibers consisting of polyolefin (Pg. 11, Line 3) coated with a hydrophilic polymer (Pg. 11, Lines 16-22).

As to **Claim 8**, BORMANN discloses said hydrophilic polymer is acrylic polymers (Pg. 14, Lines 13-19).

As to **Claim 9**, BORMANN discloses a filter device including porous elements made of polybutylene terephthalate (Pg. 11, Lines 1-5), where first porous element can be coated with a hydrophilic polymer and the second element can be uncoated (Pg. 11, Lines 15-28).

As to **Claim 10**, BORMANN discloses the porous elements are arranged in the filter device according to a decreasing value of the CWST (Pg. 12, Lines 2-5), from inlet to outlet (Pg. 12, Lines 10-15, Figs. 1-3).

As to **Claim 16**, BORMANN discloses a blood bag device for the separation of blood into leukocyte depleted blood components (Fig. 4) comprising a first bag (51), in

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fluid flow communication with a second bag (50) through a leukocyte filter device (100) according to **claim 1** (see 102/103 rejection of **Claim 1**).

As to **Claim 17**, BORMANN discloses a method for leukocyte depletion of blood products comprising feeding said blood product through a filter device (Claim 29) according to **claim 1** (see 102/103 rejection of **Claim 1**).

As to **Claim 18**, BORMANN discloses said blood product is plasma (Claim 9).

Claim Rejections - 35 USC § 103

4. **Claims 4-5 are rejected under 35 U.S.C. 103(a) as obvious over WO00/54873, BORMANN et al. in view of US Patent No. 4,925,572, PALL.**

As to **Claims 4-5**, BORMANN discloses layers of filtering material in the porous element (Pg. 11, Lines 12-14). BORMANN does not appear to explicitly disclose that the layers are made of the same material and subsequently have the same hydrophilicity properties. However, PALL discloses the use of multiple layers in a filter element made of the same material and the material inherently has the same hydrophilicity properties, absent evidence to the contrary (C28/L7-14); and that the filter elements can have different and varied pore structures (Pg. 16, Lines 4-5).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the filter material of the layers of BORMANN to include layers of the same material of PALL. The suggestion would have been that PALL discloses layers having a decreasing pore size from inlet to outlet (C15/L55-59) to efficiently remove

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microaggregates and leukocytes. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

5. **Claim 6 is rejected under 35 USC 103 (a) as being obvious over WO00/54873, BORMANN et al. in view of US Patent No. 5,298,165, OKA et al..**

As to **Claim 6**, BORMANN discloses that the filter elements can have different and varied pore structures (Pg. 16, Lines 4-5). BORMANN does not appear to explicitly disclose that the filter elements have decreasing pore size from inlet to outlet. However, OKA discloses two layers have a decreasing pore size from inlet to outlet, where the filtering material has a pore size higher than its successive porous element (OKA, Claims 1-2).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the different pore structures of the filter elements of BORMANN to include the decreasing pore size from inlet to outlet of the porous elements of OKA. The motivation would have been to more effectively remove leukocytes from a blood product (Abstract). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

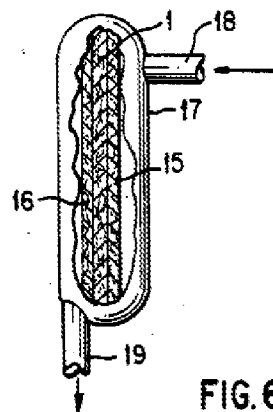
6. **Claims 14-15, 19 are rejected under 35 USC 103 (a) as being obvious over WO00/54873, BORMANN et al. in view of US Patent No. 5,190,657, HEAGLE et al..**

As to **Claims 14, 19**, BORMANN discloses the filter device and filtration elements for leukocyte depletion as shown in the 102/103 rejection of **Claim 1**.

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BORMANN does not appear to explicitly disclose the use of a filtration element which is not adapted for leukocyte removal. However, HEAGLE discloses a pre-filter (Fig. 6, Ref. 15) which is not adapted for leukocyte removal and instead remove of agglomerates, the pre-filter is made from woven, non-woven textile materials or metal meshes [*microaggregate filtration elements*] (C14/L9-16).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the filtration device for leukocyte depletion of BORMANN to include the pre-filter element which is not adapted for leukocyte removal of HEAGLE. The suggestion would have been to remove large agglomerates prior to contact with the filter element (C14/L9-16). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.



As to **Claim 15**, HEAGLE discloses said filter elements not adapted for leukocyte removal (15) are located closer to the inlet (18) than said elements adapted for leukocyte removal (1).

Response to Arguments

7. Applicant's arguments filed 10/1/2009 have been fully considered but they are not persuasive in view of the new grounds of rejection necessitated by amendment.

Applicant argues that because BORMANN discloses filter layers with alternating hydrophilicity profiles it does not anticipate or render obvious the claims. It appears Applicant argues that MAJUREL is in a different field of endeavor or does not disclose the Applicant's invention. Neither argument is found persuasive. As examiner has pointed out in the office action BORMANN discloses that the filter elements have different hydrophilicity characteristics (see rejection of Claims 1, 20-21, specifically Pg. 12), which anticipates or renders obvious the invention, especially in light MAJUREL. MAJUREL teaches that it is well known in the field of blood separation to have a gradient hydrophilicity profile from the inlet to the outlet. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Additional arguments are not persuasive in light of the new grounds of rejection necessitated by amendment.

Conclusion

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8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- US Patent No. 4,880,548 as it discloses a CWST of the filter element of 90dyn/cm;
- US Patent No. 4,985,153 as it discloses layers of filter material for leukocyte depletion; and
- US Patent No. 5,229,012 discloses as it discloses a CWST between 10-20dyn/cm for a leukocyte depletion filter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone /number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

MC